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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/675,828	09/29/2000	Thomas J. Cummins	CDS-266	1041

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EXAMINER

STRZELECKA, TERESA E

ART UNIT PAPER NUMBER

1637

DATE MAILED: 02/21/2003

18

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/675,828	CUMMINS ET AL.
	Examiner	Art Unit
	Teresa E Strzelecka	1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 25 November 2002.

2a) This action is FINAL.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 28,29,33 and 36 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 28,29,33 and 36 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____	6) <input type="checkbox"/> Other: _____

### **DETAILED ACTION**

1. This Office action is in response to an amendment filed on November 25, 2002. Applicants amended claims 33 and 36. Claims 28, 29, 33 and 36 are pending and will be examined. Claims 33 and 36 are independent claims, claims 28 and 29 depend from claim 33.
2. In view of Applicants amendments rejections of claims 33, 28, 29 and 36 under 35 U.S.C. 112 are withdrawn. Rejection of claims 33, 28 and 29 under 35 U.S.C. 102(e) are withdrawn.
3. This Office action is made non-final because of new grounds of rejection.

#### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 33, 28, 29 and 36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 33 and 36 are indefinite over the recitation of the limitations "... first and second nucleic acid sequences ... which are separated from each other along said opposing strands by from 90 to 400 nucleotides..." and "... third and fourth nucleic acid sequences being different from said first and second nucleic acid sequences and being separated from each other along said opposing strands ... by from 90 to 400 nucleotides..." (emphasis added). It is not clear how the separation of the first and second, or third and fourth nucleic acid sequences is determined. These sequences are complementary to first and second, or third and fourth, respectively, primer sequences. A primer has a 5' end, N nucleotides and a 3' end. Therefore a distance between two primer-complementary sequences can be measured, for example, either between the 5' ends of the first and second primer (or third and fourth primer) or between the 3' ends of the first and second primer (or third and

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fourth primer). In the first case the separation between the first and second sequences would be larger from the separation obtained in the second case by the sum of nucleotides present in each primer. For example, if 5'-5' separation is 400 bp, and each primer has 20 bp, the 3'-3' separation would be 360 bp.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claim 36 is rejected under 35 U.S.C. 102(b) as being anticipated by Frank et al. (Methods in Pathology, vol. 5, pp. 449-454, 1992; cited in the IDS) as evidenced by Promega Catalog (page 67, 1993-93).

Frank et al. teach simultaneous amplification and simultaneous detection of three different target nucleic acids using three different primer pairs. The target nucleic acids are: 1) cytomegalovirus (CMV) major immediate early (MIE) gene, 2) CMV late antigen gp64 (LA) gene and 3) human  $\beta$ -hemoglobin gene (page 449, third paragraph).

Primers used for the amplification of these three sequences are listed in Table 1. Only primers used in the first round of amplification were considered with respect to their length, melting temperature ( $T_m$ ) and the length of the amplification product (which corresponds to the 5'-5' end separation of the primers). Primer melting temperatures were calculated using formula (I) given on page 12, line 30.

<u>Primer</u>	<u>Primer length, bp</u>	<u>T<sub>m</sub>, °C</u>	<u>Product size, bp</u>
CMV MIE 5'	20	73.25	162
CMV MIE 3'	20	73.25	
CMV LA 5'	22	69.6	132
CMV LA 3'	21	71.4	
Hemoglobin 5'	22	69.6	210
Hemoglobin 3'	23	69.5	

Therefore, primer sets for CMV LA and hemoglobin satisfy the requirements of having melting temperatures within 2°C of each other, the lengths of each pair of primers are within 5 bp from each other, and their separation (as measured by the amplification product size) is within the range of 90 to 400 bp.

Frank et al. teach using these primers in a PCR reaction which contained 200 µM of each dNTP, 10% of 10x Taq DNA polymerase buffer (from Promega) and 5 units of Taq polymerase. The PCR reaction parameters for the first round included 2 minutes at 64°C for primer annealing and 2 minutes at 72°C for primer extension (page 450, paragraphs 3 and 4). The amplification products were simultaneously detected by electrophoresis on a 3% NuSieve/1% agarose gel containing 0.5 µg/mL ethidium bromide.

Frank et al. do not explicitly teach Taq DNA polymerase cofactor, Mg<sup>2+</sup> or Mn<sup>2+</sup>. Frank et al. teach using 10x Taq polymerase buffer from Promega. As evidenced by 1992-93 Promega catalog, 10x polymerase buffer contained MgCl<sub>2</sub> (page 67).

### ***Double Patenting***

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir.

1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claim 33 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 14 of U.S. Patent No. 6,174,668 in view of Tavernarakis et al. (U.S. Patent No. 5,569,582).

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claims. See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

Claim 14 of U.S. Patent No. 6,174,668 recites a method of simultaneous amplification and detection of two target DNA samples. The method of claim 14 differs from claim 33 herein in that it fails to disclose priming (=annealing) and primer extension reactions being carried out at the same temperature from within the range of 65 to 72 °C.

Tavernarakis et al. teach PCR amplification method in which both the annealing and amplification steps are carried out at the same temperature, which may range from 68 °C to 80 °C, preferably about 70 °C (col. 6, lines 14-27; col. 8, lines 22-25; col. 11, lines 28-34).

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to have modified the method of claim 14 of U.S. Patent No. 6,174,668 to

include single temperature of Tavernarakis et al. for the annealing and extension steps. The motivation to do so, expressly provided by Tavernarakis et al., would have been that using single temperature provided for faster cycling of the reactions and increased priming specificity (col. 3, lines 1-8).

10. Claim 36 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 2 of U.S. Patent No. 6,174,668 in view of Tavernarakis et al. (U.S. Patent No. 5,569,582).

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claims. See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

Claim 2 of U.S. Patent No. 6,174,668 recites a method of simultaneous amplification and detection of two target DNA samples. The method of claim 2 differs from claim 36 herein in that it fails to disclose priming (=annealing) and primer extension reactions being carried out at the same temperature from within the range of 65 to 72 °C.

Tavernarakis et al. teach PCR amplification method in which both the annealing and amplification steps are carried out at the same temperature, which may range from 68 °C to 80 °C, preferably about 70 °C (col. 6, lines 14-27; col. 8, lines 22-25; col. 11, lines 28-34).

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to have modified the method of claim 2 of U.S. Patent No. 6,174,668 to include single temperature of Tavernarakis et al. for the annealing and extension steps. The

motivation to do so, expressly provided by Tavernarakis et al., would have been that using single temperature provided for faster cycling of the reactions and increased priming specificity (col. 3, lines 1-8).

No references were found teaching or suggesting claims 33, 28 and 29, but they are rejected for reasons given above.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teresa E Strzelecka whose telephone number is (703) 306-5877. The examiner can normally be reached on M-F (8:30-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

  
GARY BENZION, PH.D  
SUPERVISORY PATENT EXAMINER  
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February 11, 2003

TS

  
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